

SPRING 2007

Maryland Board of Pharmacy news

In This Issue:

- Licensing Corner—2
- Maryland Legislative Session of Importance—3
- Prescription Drug Repository Update—4
- Practice Committee Corner F.A.Q—5
- Information Station F.A.Q.—6
- Notice of Opportunity for Dispensing of Prescription Drugs—7

The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality health care in the field of pharmacy through licensing pharmacists and issuing permits to pharmacies, and distributors, setting standards for the practice of pharmacy through regulations and legislation, educating consumers, and receiving and resolving complaints from the public regarding pharmacists, pharmacies, and distributors.

**4201 Patterson Avenue
Baltimore, Maryland 21215**

Tel: 410.764.4755

Fax: 410.358.6207

Toll Free: 800.542.4964

TTY: BALTO.383.7555



FROM THE EXECUTIVE DIRECTOR'S DESK

It Ain't Easy...And I Didn't Say It Was

April 2nd marks the start of the Board's 106th year. If the first 99 years were anything like the past seven, then celebration is well deserved. During the last seven-year period, over fifty sets of regulations have been created or revised. Board oversight responsibilities have significantly increased, to include the areas of pharmacy technicians, pharmacist administration of influenza vaccines, prescription repositories, drug therapy management, patient safety, pharmacy establishment inspections and direct monitoring of impaired pharmacists under Board orders.

The Board's website now offers on-line renewals in addition to up-to-date information about Board activities, links to other sites, verification of licenses and permits, complaint submissions, and completion and downloading of forms. Also, the Board has led the other Health Occupation Boards in the recruitment and training of volunteer practitioners for emergency preparedness and in outreach to consumers through participation in events such as the Flower Mart and State Fair to encourage self-advocacy and self-monitoring by pharmacy patients.

Board accomplishments were achieved in partnership with the Department of Health and Mental Hygiene (the Department). Over the past seven years, the Board has worked to emphasize the need to address gaps in pharmacy and wholesale distribu-

tor monitoring, as well as to strengthen oversight of licensed practitioners in Maryland. The Department has supported legislation and other initiatives to provide the Board with the authority to do so. However during these contemporary times, if approaches selected to implement new initiatives are not successful, the consequences may be more harmful to Maryland patients than they were a hundred years ago.

For example, legislation to tighten oversight of wholesale distributors licensed in Maryland was passed this April. It took over three years of formal and informal meetings between all stakeholders to develop legislation that will help insure that only legitimate drugs are distributed into and out of Maryland. After regulations are promulgated, the challenge will be in the Board's ability to enforce them. The Board and Department will need to agree on the best approach to guarantee a safe prescription drug distribution system in Maryland.

The Board currently has a vacancy for its Pharmacist Compliance Officer position and seeks a qualified pharmacist to refine the framework for existing responsibilities and to help develop and manage new systems designed to meet statutory responsibilities (monitoring pharmacists and pharmacy

Continued on page 2

FROM THE EXECUTIVE DIRECTOR'S DESK

...continued from page 1

technicians, greater monitoring of distributors, direct monitoring of persons under drug rehabilitation orders, and inspections of pharmacies and distributorships).

My mother used to describe her long-term marriage in this manner "It ain't easy...and I didn't say it wasn't." She meant that her marriage was working, but not without an **on-going challenges**. The Board and Department have undertaken many new initiatives, resulting in a temporary strain on the Board's operational infrastructure. A solid infrastructure is essential to a marriage as well as to units of government that work together.

Most recently, former Senator Paula Hollinger has been appointed as *Associate Director, Health Workforce* by

Department Secretary John Colmers. She will review personnel and other challenges at the Board of Pharmacy (as well as those of all of the other Health Occupation Boards) to assist the Department in addressing current needs.

The Board of Pharmacy welcomes Senator Hollinger and looks forward to her leadership to strengthen the Department's and Board's partnership as they continue working together to protect Maryland consumers' health care needs.

Enjoy your Spring.

LaVerne Naesea

LICENSING CORNER

Update on Pharmacy Technician Registration

The proposed regulations for the Pharmacy Technician Registration and the Notice of Emergency Action were posted in the *Maryland Register* on May 11, 2007. Entities requiring approval of Training Programs or Technician Examinations are encouraged to submit applications for Board approval once the emergency regulations are promulgated. Applications and instructions for applying for the approval of both programs will be posted on the Board website when they become available.

The Board is in the process of developing a suggested schedule for submissions of technician applications based on location and type of technician employee. Eligible pharmacy technicians and students may submit applications after the emergency regulations are published, but they will not be required to register until after the non-emergency proposed regulations are promulgated. (See article in this newsletter entitled *Pharmacy Technician Emergency and Non-emergency Proposed regulations*)

Following promulgation of the *Emergency Regulations*, pharmacy technicians and pharmacy students may obtain applications from the Board's website (www.mdbop.org), along with instructions on how to obtain criminal background checks. Applications or Criminal Background Check forms will be mailed upon receipt of requests from pharmacy technicians and students. The Board will notify the public when technician and student registration becomes mandatory.

There are three primary ways that a Pharmacy Technician may apply with the Maryland Board of Pharmacy: 1) If a national technician certification program certifies the pharmacy technician and the applicant submits to a *Criminal Background Check*; 2) If a technician has worked in the pharmacy area of a pharmacy operated by the same pharmacy permit holder since January 1, 2006 and the applicant submits to a *Criminal Background Check*; or 3) If the pharmacy technician has completed a Board approved pharmacy technician-training program and Board approved examination and submits to a *Criminal Background Check*.

Most likely pharmacy technicians who can meet the first and second methods will be the only immediately eligible applicants after the *Emergency Regulations* are promulgated. Pharmacy students performing pharmacy technician functions and who are not in a school of pharmacy sanctioned experiential learning program must submit applications for exemption from the registration requirements. (Other application requirements, including an initial application fee of \$45.00 must be met in addition to those noted above.)

For more information and updates on the Pharmacy Technician Regulations, please refer to the Board's website at www.mdbop.org. Go to the homepage and click on the Pharmacy Technician Registration process located under "What's New." ■

2007 MARYLAND LEGISLATIVE SESSION BILLS OF IMPORTANCE TO THE MARYLAND BOARD OF PHARMACY

2007 Maryland Legislative Session Bills of Importance to the Maryland Board of Pharmacy

Below are the results of the 2007 Legislative Session Bills of Importance to the Maryland Board of Pharmacy. Cross-filed bills are listed together.

Bill #	Bill Name	Result
SB 47	State Government – Administrative Procedure Act – Scope of Judicial Review	FAILED
HB 237	State Government – Administrative Procedure Act – Scope of Judicial Review	FAILED
HB 100	Health Occupations – Cultural Competency Workgroup	WITHDRAWN
HB 123	Consumer Protection – Personal Information Protection Act	FAILED
SB 904	Consumer Protection – Personal Information Protection Act	FAILED
HB 141	State Board of Pharmacy - Sending Renewal Notices by Electronic Means	PASSED
HB 210	Consumer Protection - Sale or Distribution of Personal Information – Limitations	WITHDRAWN
HB 236	Health Occupations - Registered Nurses – Dispensing Methadone	PASSED
SB 266	Prescription Privacy Act	FAILED
SB 349	Disease Prevention - Sexually Transmitted Diseases - Expedited Partner Therapy	PASSED
HB 769	Disease Prevention - Sexually Transmitted Diseases - Expedited Partner Therapy	PASSED
SB 670	Prescription Drugs – Canadian Mail Order Plan	FAILED
SB 677	Pharmacy Benefit Managers Regulation Act	FAILED
HB 734	Pharmacy Benefit Managers Regulation Act	FAILED
HB 736	State Board of Pharmacy - Job Classifications and Grades for Staff	FAILED
SB 1013	State Board of Pharmacy - Job Classifications and Grades for Staff	FAILED
HB 820	Health Occupation Boards - Determination of Job Classifications and Grades for Staff	FAILED
SB 939	Controlled Dangerous Substances – Dextromethorphan Products	FAILED
HB 1030	State Board of Pharmacy - Wholesale Drug Distribution - Permit Requirements	PASSED
SB 759	State Board of Pharmacy - Wholesale Drug Distribution - Permit Requirements	PASSED
HB 1169	Health Programs - Diabetes - The Maryland P3 Program	WITHDRAWN

PRESCRIPTION DRUG REPOSITORY UPDATE

By Anna Jeffers, Legislation and Regulations Manager

The Prescription Drug Repository Program became effective, with the passage of SB 1059, on July 1, 2006. It allows individuals or their representatives to return unused, non-controlled, prescribed medications under certain circumstances. The regulations to implement the Prescription Drug Repository Program, COMAR 10.34.33.01 - 12, became effective on January 29, 2007. Post cards announcing the initiation of the Program were mailed to permit holders on February 28, 2007 to solicit their volunteer participation. The Board is ready to begin accepting applications from permit holders willing to volunteer for this Program.

You may access information regarding this Program on the Board's website at: www.mdbop.org. On the homepage, scroll down to "What's New" and click on "Prescription Drug Repository Program" under "Legislation/Regulation Information." There you will find a link to COMAR 10.34.33.01 - .12, three Program forms, the Task Force Report and the Annual Report.

The *Prescription Drug Repository Program Application* is to be completed by a permit holder or health care facility that is interested in being a Drop-off site or a Repository. A pharmacist or other health care practitioner at the Drop-off site will place the donated items in a sealed bag with the *Prescription Drug Repository Program Donor*

Form, labeled with a control number and store the bag in a secure area accessible only to those pharmacists or health care practitioners who have been assigned the responsibility to accept donated items. The Drop-off site will then forward the sealed bags to a Repository at least every two weeks. The Drop-off site may not dispense donated items, resell them, or charge a fee for the donations.

The Repository will dispose of donated items that are ineligible drugs. The pharmacist at the Repository site will obliterate patient specific information from the prescription labels of donated items. Repositories may not resell donated items or establish or maintain a waiting list, but may charge a fee of not more than \$10 per dispensed prescription. Repositories shall maintain separate inventories for donated items; store donated items in a secure location; maintain separate prescription files for patients receiving donated items; and submit annual reports on its activities to the Board.

A *Prescription Drug Repository Recipient Form* will be required of all recipients to confirm that the recipient understands the donated items have been donated and that entities involved in the program are immune from liability. ■



PRACTICE COMMITTEE CORNER – F.A.Q.

By Dave Chason and Anna Jeffers

1. If a pharmacy permit holder sells the pharmacy after January 1, 2006, may long standing pharmacy technicians employed there still take advantage of “grandfathering?”

No, a pharmacy technician has to have worked in the pharmacy area of a pharmacy operated by the same pharmacy permit holder since January 1, 2006. See Health Occupations Article, 12-6B-02(d)(1), Annotated Code of Maryland.

2. Is a hand-carried electronically signed prescription for non-CDS and CIII - CV a valid prescription?

No. A hand carried electronically signed prescription for non CDS and CIII - CV is not acceptable under the Code of Maryland Regulations (COMAR). A prescription, no matter how generated, is no longer an electronic prescription once it is handed to the patient. COMAR 10.34.20.02B(1) indicates that a prescription handed to a patient must contain the signature of the prescriber. The requirement of signatures for CDS prescriptions handed to the patient is set forth in COMAR 10.19.03.08 for Schedule II and 10.19.03.09 for Schedule III - V.

3. What are the procedures and regulations in regards to a relocation of a pharmacy that is undergoing renovation/remodeling?

A permit is not required for remodeling in Maryland if the pharmacy is relocated in the same building/same floor during the remodeling project. The permit holder is required, however, to notify the Board of the remodeling and contact the Board upon completion of the project so that a new inspection may be performed.

If the permit holder relocates the pharmacy to a new address/new building during the remodeling project, then the permit holder must apply for a new permit due to that location change.

4. What are the laws and regulations regarding interior and exterior pharmacy signs?

Maryland law does not restrict the wording, size or location of signs for a pharmacy.

The Board, however, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee advertises or otherwise publicly claims to dispense prescriptions or practice pharmacy in a superior manner. In addition, a licensee may not advertise in a manner that tends to deceive or defraud the public. See Health Occupations Article, § 12313(b)(18) and (19), Annotated Code of Maryland.

The Maryland Food, Drugs and Cosmetics Act further addresses advertising of a food, drug, device or cosmetic. If an advertisement is alleged to be false because it is misleading, it will be taken into account the representations made or suggested by statement, word, design, symbol, or sound, alone or in combination; and the extent to which the labeling or advertisement fails to reveal consequences that may result from use of the substance. Please refer to HealthGeneral Article, §§ 21101, 21102, 21247 and 21260.

Upon the closure of a pharmacy, the pharmacy permit holder shall remove or completely cover all indications (including signs) that the premise was a pharmacy within 30 days after the date the licensed pharmacy ceases to operate as a pharmacy. See the Code of Maryland Regulations (COMAR) 10.34.14.03.

5. Is a pharmacist required to check the identification of customers picking up a prescription for a controlled dangerous substance?

The Maryland Pharmacy Act does not require identification from customers upon picking up their prescriptions. A pharmacist may, however, require identification if the decision is based on professional judgment, experience or knowledge that the prescription may not be valid.

Continued on page 6

INFORMATION STATION

Attention Foreign Graduates – NABP Announces Pre-FPGEE Suspended until September 2007

Effective immediately, NABP has suspended the Pre-FPGEE, the practice examination that familiarizes Foreign Pharmacy Graduate Equivalency Examination (FPGEE) applicants with the FPGEE testing experience.

The suspension of the Pre-FPGEE is necessitated by the updating of the FPGEE blueprint, which was recently approved by the Advisory Committee on Examinations and the NABP Executive Committee. Since the June 2007 FPGEE administration will be based on the updated blueprint, a score for the

present Pre-FPGEE (based on the current blueprint) would not be an accurate indicator of how an examinee would perform on the FPGEE. An updated Pre-FPGEE will be available in September 2007.

Applicants will no longer be able to access the examination on the NABP Web site; however, the Pre-FPGEE FAQ section is still available and indicates that the Pre-FPGEE has been suspended. If you have any questions, please contact NABP customer service at 847-391-4406 or via e-mail at custserv@nabp.net. ■

Maryland Pharmacists Duty to Report

According to COMAR 34.10.05, pharmacists have a legal obligation to report any suspected pharmacist misconduct that involves drugs and/or alcohol abuse or dependency. If signs of impairment in a pharmacist are suspected, please contact the Pharmacist Education and Assistance Committee (PEAC), a non-profit organization which provides confidential support and advocacy to Maryland pharmacists. If you are aware of conduct that involves drug abuse or drug dependency, you must report that pharmacist to PEAC.

Reporting pharmacists to PEAC is confidential and it protects you, your fellow pharmacists and the community at large. Failure to report such a case violates Maryland Pharmacy Regulations and could subject you to discipline by the Maryland Board of Pharmacy.

Please visit PEAC's website at www.peacmaryland.org for more information and to learn how to recognize the signs of drug or alcohol impairment in a fellow pharmacist. ■

PRACTICE COMMITTEE CORNER – F.A.Q.

...continued from page 5

**** Notice ****

Please be advised that the responses above were prepared with the knowledge of only the facts presented. The responses are not intended to be legal advice. Although references to current laws and regulations may be included in the responses, keep in mind that laws may change annually and regulations may be changed at any time. Further, the information provided is based on State pharmacy laws and regulations. Federal rules and State requirements that are not included under the Maryland Pharmacy Practice Act, however, may also apply. To insure that all current applicable laws have been considered, you may want to consult with your own legal counsel. ■

NOTICE OF OPPORTUNITY FOR COMMENT REGARDING SUBTITLE 13 DRUGS CHAPTER 01 DISPENSING OF PRESCRIPTION DRUGS BY A LICENSEE

In accordance with the Regulatory Review and Evaluation Act, State Government Article, §§10-130–10-139, Annotated Code of Maryland, the Maryland Board of Pharmacy under the Department of Health and Mental Hygiene currently is reviewing and evaluating the following regulations codified in Title 10, Subtitle 13, Annotated Code of Maryland, of the Code of Maryland Regulations (COMAR) 10.13.01 Dispensing of Prescription Drugs by a Licensee. This review process occurs every 8 years.

These regulations define the parameters under which a licensed physician, dentist or podiatrist may dispense prescription drugs. Please see pages 272 and 273 of the 2006 Edition of the Maryland Pharmacy Laws Book to review the regulations.

The Maryland Board of Pharmacy would like to provide interested parties with an opportunity to participate in the review and evaluation process by submitting comments on the regulations. All parties interested in participating in this process may submit comments by mail to Anna D. Jeffers, Legislation and Regulations Manager, Maryland Board of Pharmacy, 4201 Patterson Avenue, Baltimore, MD 21215, by fax to (410) 358-6207, or by email to adjeffers@dhmh.state.md.us.

An official notification of this review and evaluation will be forthcoming in the Maryland Register. The anticipated deadline for comments is no later than June 1, 2007. Parties may contact the Maryland Board of Pharmacy at (410) 764-4794 with questions about this process. ■

DISCIPLINARY CASES

Steven Sodipo, License #11532

Effective January 5, 2007, Ordered Continuing Summary Suspension.

Callixtus Onigbo Nwaehiri, PD, License #10899

Effective January 5, 2007, Ordered Continuing Summary Suspension.

Newcare Home Health Services, Inc., Permit #PW101/D00652

Effective January 5, 2007: Order for Summary Suspension; Prohibited from operating as a pharmacy or distributing prescription drugs in the state of Maryland.

Jeffrey Yannello, License #10644

Effective February 15, 2007, Final Decision and Order: that his license to practice pharmacy be suspended for three (3 years), with one (1) year stayed, followed by probation. ■



Maryland Board of Pharmacy

How are we doing?

Please telephone or e-mail the Board staff your questions and comments.

Telephone: 410-764-4755

Licensing:	Shirley Costley	scostley@dhhm.state.md.us
Compliance:	Colin Eversley	creversley@dhhm.state.md.us
Personnel:	Patricia Gaither	pgaither@dhhm.state.md.us
Regulations:	Anna Jeffers	adjeffers@dhhm.state.md.us
Website:	Tamarra Banks	tbanks@dhhm.state.md.us
Public Relations:	Summar Goodman	sjgoodman@dhhm.state.md.us
General:	LaVerne Naesea	lnaesea@dhhm.state.md.us

Meetings

The Pharmacy Board meetings are open to the public from 9:00 a.m. – 12 noon at 4201 Patterson Avenue, Baltimore, Maryland 21215. The Board encourages all interested parties to attend. Dates are:

May 16, 2007

June 20, 2007

July 18, 2007

August 22, 2007

September 19, 2007

Address or Employment Change

Submit the *Pharmacist Change of Information form* on our website. Go to www.mdbop.org and click on *Forms & Publications*.

Special Notice

The Maryland Board of Pharmacy Newsletter is considered an official method of notification to pharmacists and pharmacies. **These Newsletters may be used in administrative hearings as proof of notification.** Please read them carefully and keep them in the back of the Maryland Pharmacy Law Book for future reference.

Editorial Committee:

Summar Goodman, Patricia Gaither, LaVerne Naesea, Jeanne Furman, Donald Taylor and Linda Bethman

Newsletter Layout and Design: Summar Goodman

*Have an Upcoming Event or Story Ideas? E-mail to sjgoodman@dhhm.state.md.us

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Maryland Board of Pharmacy

Note: Procedures for submission and approval of Pharmacy Technician Training Programs will be provided on the Board's website. Visit www.mdbop.org for details.

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4201 Patterson Avenue

Maryland Board of Pharmacy



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